DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

GE Healthcare
% Mr. Bryan Behn
Regulatory Affairs Director
9900 Innovation Drive
WAUWATOSA WI 53226

May 5, 2016

Re: K161047
Trade/Device Name: LOGIQ P9 and LOGIQ P7
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: April 12, 2016
Received: April 13, 2016

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161047

Device Name
LOGIQ P9 and LOGIQ P7

Indications for Use *(Describe)*

The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; and Intraoperative (abdominal, thoracic, vascular).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	5,6
Abdominal[1]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Small Organ[2]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Neonatal Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	5,6
Adult Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	5,6
Cardiac Adult & Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Peripheral Vascular	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Conventional	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Superficial	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Other[4]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Transvaginal	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Transuretheral											
Intraoperative[8]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with L4-12t-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric	*P	*P	*P		*P	*P	*P	*P	*P	*P	[3,6]
Small Organ[2]	*P	*P	*P		*P	*P	*P	*P	*P	*P	[3,6]
Neonatal Cephalic	*P	*P	*P		*P	*P	*P	*P	*P	*P	[3,6]
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	*P	*P	*P		*P	*P	*P	*P	*P	*P	[3,6]
Musculo-skeletal Conventional	*P	*P	*P		*P	*P	*P	*P	*P	*P	[3,6]
Musculo-skeletal Superficial	*P	*P	*P		*P	*P	*P	*P	*P	*P	[3,6]
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; *P = previously cleared by FDA in (K151028)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with L10-22-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes)
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric											
Small Organ[2]	***P**	***P**	***P**		***P**	***P**	***P**	***P**	***P**	***P**	
Neonatal Cephalic	***P**	***P**	***P**		***P**	***P**	***P**	***P**	***P**	***P**	
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional	***P**	***P**	***P**		***P**	***P**	***P**	***P**	***P**	***P**	
Musculo-skeletal Superficial	***P**	***P**	***P**		***P**	***P**	***P**	***P**	***P**	***P**	
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; *P = previously cleared by FDA in (K151028)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with L3-9i-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes)
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric											
Small Organ[2]	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Musculo-skeletal Conventional	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Musculo-skeletal Superficial	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with E8CS--RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes)
Ophthalmic											
Fetal / Obstetrics[7]	***P**	***P**	***P**		***P**	***P**	***P**	***P**	***P**	***P**	[3,6]
Abdominal[1]	***P**	***P**	***P**		***P**	***P**	***P**	***P**	***P**	***P**	[3,6]
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	***P**	***P**	***P**		***P**	***P**	***P**	***P**	***P**	***P**	[3,6]
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	***P**	***P**	***P**		***P**	***P**	***P**	***P**	***P**	***P**	[3,6]
Transvaginal	***P**	***P**	***P**		***P**	***P**	***P**	***P**	***P**	***P**	[3,6]
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; *P = previously cleared by FDA in (K160184)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with BE9CS-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes)
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	***P**	***P**	***P**		***P**	***P**	***P**	***P**	***P**	***P**	[3,6]
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	***P**	***P**	***P**		***P**	***P**	***P**	***P**	***P**	***P**	[3,6]
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; *P = previously cleared by FDA in (K160277)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with RIC5-9A-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes)
Ophthalmic											
Fetal / Obstetrics[7]	***P**	***P**	***P**		***P**	***P**	***P**	***P**	***P**	***P**	[5,6]
Abdominal[1]	***P**	***P**	***P**		***P**	***P**	***P**	***P**	***P**	***P**	[5,6]
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	***P**	***P**	***P**		***P**	***P**	***P**	***P**	***P**	***P**	[5,6]
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal	***P**	***P**	***P**		***P**	***P**	***P**	***P**	***P**	***P**	[5,6]
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; *P = previously cleared by FDA in (K160184)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with 12S-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes)
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric	***P**	***P**	***P**	***P**	***P**	***P**	***P**	***P**	***P**	***P**	
Small Organ[2]											
Neonatal Cephalic	***P**	***P**	***P**	***P**	***P**	***P**	***P**	***P**	***P**	***P**	
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; *P = previously cleared by FDA in (K160184)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with C1-5-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	5,6
Abdominal[1]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K141639, K143452)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with 4C-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	5,6
Abdominal[1]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K141639)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with 9L-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Pediatric	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Small Organ[2]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K133533)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with ML6-15-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Small Organ[2]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Neonatal Cephalic	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Superficial	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K141639, K143452)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with E8C-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes)
Ophthalmic											
Fetal / Obstetrics[7]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	5,6
Abdominal[1]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Transvaginal	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3.5,6
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K133533)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with L8-18i-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	5,6
Small Organ[2]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Neonatal Cephalic	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Superficial	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K133533)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with P8D Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic			**P**	**P**							
Cardiac Adult & Pediatric			**P**	**P**							
Peripheral Vascular			**P**	**P**							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with RAB2-6-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	5,6
Abdominal[1]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	5,6
Pediatric											
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	5,6
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K141639)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with L6-12-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes)
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Pediatric	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Small Organ[2]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Superficial	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K133034)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with 12L-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes)
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Pediatric	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Small Organ[2]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Neonatal Cephalic											
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Musculo-skeletal Superficial	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	3,5,6
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K133533)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging - Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D/4D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with 8C-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes)
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	5
Pediatric	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	5
Small Organ[2]	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	5
Neonatal Cephalic	**P**	**P**	**P**		**P**	**P**	**P**	**P**	**P**	**P**	5
Adult Cephalic											
Cardiac Adult & Pediatric											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K133533)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging – Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with 3Sc-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes)
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	5,6
Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	5,6
Small Organ[2]											
Neonatal Cephalic											
Adult Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Cardiac Adult & Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K133533)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging – Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

GE LOGIQ P9 and LOGIQ P7 with 6S-RS Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse	Other [Notes]
Ophthalmic											
Fetal / Obstetrics[7]											
Abdominal[1]											
Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Small Organ[2]											
Neonatal Cephalic	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Adult Cephalic											
Cardiac Adult & Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal[8]											
Transvaginal											
Transuretheral											
Intraoperative[8]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA (K133533)

Notes: [1] Abdominal includes Renal, GYN/Pelvic.
[2] Small organ includes breast, testes and thyroid
[3] Elastography Imaging – Elasticity.
[4] Other use includes Urology/Prostate
[5] 3D Imaging mode
[6] Needle guidance imaging
[7] Includes infertility monitoring of follicle development
[8] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV)
[*] Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription User (Per 21 CFR 801.109)

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	April 12, 2016
Submitter:	GE Healthcare 9900 Innovation Dr Wauwatosa, WI 53226
Primary Contact Person:	Bryan Behn Regulatory Affairs Director GE Healthcare T:(414)721-4214 F:(414)918-8275
Secondary Contact Person:	Chan Sook Kim Regulatory Affairs Leader GE Healthcare GE Ultrasound Korea, Ltd. T: +82 31 740 6307
Device: Trade Name:	LOGIQ P9 and LOGIQ P7
Common/Usual Name:	LOGIQ P9 and LOGIQ P7
Classification Names: Product Code:	Class II Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX
Primary Predicate Device:	K143452 LOGIQ P9/P7 Diagnostic Ultrasound System
Reference Predicate Devices:	K160182 LOGIQ S7 Expert Diagnostic Ultrasound System K151028 LOGIQ e Diagnostic Ultrasound System K152309 LOGIQ E9 Diagnostic Ultrasound System K160277 LOGIQ F Series Diagnostic Ultrasound System K160184 VOLUSON S Series Diagnostic Ultrasound System
Device Description:	The LOGIQ P9 and LOGIQ P7 is a full featured, general purpose diagnostic ultrasound system which consists of a mobile console approximately 53 cm wide, 69 cm deep and 157 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, 10.4-inch LCD touch screen and color 21.5-inch LCD image display.

Intended Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; and Intraoperative (abdominal, thoracic, vascular).

Technology: The LOGIQ P9 and LOGIQ P7 employs the same fundamental scientific technology as its predicate devices

Determination of Substantial Equivalence:

Comparison to Predicate Devices

The LOGIQ P9 and P7 systems are substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The LOGIQ P9/P7 and predicate LOGIQ P9/P7 systems have the same clinical intended uses.
- The LOGIQ P9/P7 and predicate LOGIQ P9/P7 systems have the same imaging modes.
- The LOGIQ P9/P7 and predicate LOGIQ P9/P7 systems transducers are identical except for the addition of 7 new transducers L4-12t-RS and L10-22-RS (identical to Logiq E series K151028), L3-9i-RS (smilar to L3-9i-D on predicate Logiq E9 K152309), BE9CS-RS (identical to Logiq F series K160277), E8CS-RS, RIC5-9A-RS, and 12S-RS (identical to Voluson S series K160184).
- The LOGIQ P9/P7 and predicate LOGIQ P9/P7 systems have the same indications for use
- The systems are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The systems have acoustic power levels which are below the applicable FDA limits.
- The LOGIQ P9/P7 and predicate LOGIQ P9/P7 systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The LOGIQ P9/P7 and predicate LOGIQ P9/P7 systems have been designed in compliance with approved electrical and physical safety standards.

- The LOGIQ P9/P7 adds an off-line scanning mode by using a battery power (AC unplugged). (previously cleared with K160182).
- The LOGIQ P9/P7 adds software features called STIC (Spatio-Temporal Image Correlation) and OmniView. (previously cleared with K160182).
- The LOGIQ P9/P7 adds a general measurement tool called Cardiac AFI (Automated Function Imaging). (previously cleared with K160182).
- The LOGIQ P9/P7 adds an customizing e-mail service to the system to allow users to send images and text via SMTP (Simple Mail Transfer Protocol) (previously cleared with K160182).

Summary of Non-Clinical Tests:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. LOGIQ P9 and LOGIQ P7 and its applications comply with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005/C1:2012
- IEC60601-1-2, Medical Electrical Equipment – Part 1-2:General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility Requirements and Tests 2007
- IEC60601-2-37, Medical Electrical Equipment – Part 2-37:Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, 2007
- NEMA UD 3, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment:2004
- ISO10993-1, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing- Third Edition, 2009
- NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment:2004
- ISO14971, Application of risk management to medical

devices: Second edition 2007

- NEMA PS 3.1 - 3.20 (2011), Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)

The following quality assurance measures are applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, LOGIQ P9 and LOGIQ P7, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the LOGIQ P9 and LOGIQ P7 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).